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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/549,342	04/13/00	COLPITTS	T 5972.US.P6

EXAMINER	
HARRIS	
ART UNIT	PAPER NUMBER
1642	10

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DEPT. 377 - AP6D-2
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DATE MAILED: 09/17/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary	Application No.	Applicant(s)	
	09/549,342	COLPITTS ET AL.	
	Examiner	Art Unit	
	Alana M. Harris, Ph.D.	1642	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-7 and 39-47* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-7 and 39-47* is/are rejected.

7)☒ Claim(s) *5, 7 and 40* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *13 April 2000* is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☒ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *2, 5 & 7* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

Election/Restrictions

1. Applicant's election of Group I (claims 1-7 and 39-47) in Paper No. 9 (filed July 3, 2001) is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

2. Claims 1-7 and 39-47 are pending.

Claims 8-38 and 48-78 have been cancelled.

Claims 1-7 and 39-47 are examined on the merits.

Priority

3. Applicants' claim for domestic priority under 35 U.S.C. 120 is acknowledged. However, the U.S. patent applications upon which priority is claimed fail to provide adequate support for all the claims of this application. None of the U.S. patent applications disclose all three of the sequences (SEQ ID NO: 2, SEQ ID NO: 3 and SEQ ID NO: 10). Hence the instant application's priority date is the effective filing date, April 13, 2000.

4. Both, the first line of the specification and the declaration reference U.S. serial number 08/215,818 in the continuing data, however the number should be 09/215,818. Both sets of information should reflect that this application is now a U.S. Patent.

Drawings

5. The drawings are objected to because of reasons cited on attached form PTO 948 completed by draftsman. Correction is required.

Claim Objections

6. Claim 5 is objected to because of the following informality: it contains reference to an amino acid residue, but no identifying sequence identification number. Appropriate correction is required.

7. Claims 7 and 40 are objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claims, or amend the claims to place the claims in proper dependent form, or rewrite the claims in independent form.

Claims 1 and 39 read on an antigen and composition comprising entire polypeptides, designated as SEQ ID NO: 2, 3 and 10, however claims 7 and 40 broadly recite polypeptides that have at least 20% identity with the amino acid sequences designated as SEQ ID NO: 2, 3 and 10. This is not further limiting from claims 1 and 39.

Claim Rej ctions - 35 USC § 112

8. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

9. Claims 7 and 40-47 are rejected under 35 U.S.C. 112, first paragraph, because the specification does not reasonably provide enablement commensurate with the scope of the claimed invention. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to practice the invention commensurate in scope with these claims.

Claims 7, 40-42, 46 and 47 are broadly drawn to "at least 20% identity with an amino acid sequence selected from the group consisting of SEQ ID NO: 2, SEQ ID NO: 3 and SEQ ID NO: 10, and fragments thereof. ". The specification while being enabling for the polypeptides having the amino acid sequences of SEQ ID NO: 2, 3 and 10, does not reasonably provide enablement for variants that have at least 20% sequence identity. There is no guidance as to how to make these divergent sequences, which possess function with the absence of any information on what functions the native protein possesses. Likewise, it would seem that specific function(s) would be required to make a protein useful for the applications disclosed in the specification. The specification does not teach what those are or how to determine what they are. This could possibly be a vast collection of polypeptides and the specification provides inadequate instruction to allow one skilled in the art to make and use the said naturally

occurring polypeptides having at least 20% sequence identity with a reasonable expectation of success and without undue experimentation.

10. Claims 7 and 40-47 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a multimeric polypeptide (MPA) consisting of EU250 (SEQ ID NO:3), BU101 (SEQ ID NO:2) and TU104 (SEQ ID NO:10) does not reasonably provide enablement for a MPA consisting of arbitrary fragments of the said sequences. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to practice the invention commensurate in scope with these claims.

The MPA of the invention is regarded as an uterglobin complex that "...will enable the identification of certain markers as indicative of a reproductive tissue disease or condition, for example, uterine cancer" and this information will be useful in detecting, diagnosing, staging, monitoring or preventing said condition. One skilled in the art could not expect that any combination of fragments of different peptide lengths and conformations would enable the practical uses of Applicants' invention. In the absence of these considerations, there is not assurance that the fragment combinations would be applicable to uses stated in the specification. It is well known that even a slight modification in peptide structure can drastically alter function. Function would be impaired if the proper number of peptide residues needed to enable Applicants' invention were not present in the MPA. The specification exemplifies no examples of the effective use of the effective use of the polypeptide as a pharmacological agent and

no such uses are art known. The claimed fragments possibly would not be selective and specific in their application of treating or preventing uterine cancer when the specification only defines specific sequences. Accordingly, those skilled in the art cannot rely on any fragment combination to implement the processes of diagnosing, prognosticating, treating or preventing uterine cancer.

Due to the unpredictability of the art one of ordinary skill in the art would not be able to select all the possible fragment combinations with a reasonable expectation of success and without undue experimentation that would function in the manner pertinent to Applicants' invention.

11. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

12. Claims 1-7 and 39-47 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

a. Claims 1-7 and 39-47 are vague and indefinite. The recitations "EU250" and "TU104" are abbreviations whose identities are not well known in the art. The applicant is advised to amend the claims to include the full terminology and functional or physical properties that characterize these polypeptides.

Claim Rejections - 35 USC § 103

13. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

14. Claims 1-7 and 39-47 are rejected under 35 U.S.C. 103(a) as being unpatentable over by U.S. Patent number 6,066,724 (filed March 21, 1997). Due to the broadness of claims 7 and 40 the rejection is set forth as follows: U.S. Patent #6,066,724 teaches polypeptides comprising variants or derivatives of Applicants sequences identified as SEQ ID NO: 3, 2 and 10, which intrinsically may or may not contain unknown polypeptides (column 16, lines 13-16). U.S. Patent #6,066,724 teaches polypeptides comprising fragments of hESF I and II identified within the patent as SEQ ID NO: 2 and 4, respectively (see column 16, lines 6-16). These polypeptides (SEQ ID NO: 4 and 2) are the same as Applicants' claimed SEQ ID NO: 3 and 2, respectively (see attached database sheets). The patent's hESF III polypeptide (SEQ ID NO: 6) shares at least 20% identity with Applicants' amino acid sequence, SEQ ID NO: 10, as evidenced in the attached database sheet.

This patent teaches both, polyclonal or monoclonal antibodies produced by the use of the polypeptides, their fragments or other derivatives the three hESF proteins (column 26, lines 33-40).

It is the Examiner's position that the polypeptides in combination as a multimeric polypeptide antigen (MPA) would have an isoelectric point of about less than 8 and a molecular weight of about 20 to 70 kilodaltons. As indicated in column 11, lines 29-33, 39-43 and 48-52 taught are the molecular weights of the three hESF polypeptides. These molecular weights are within the range of Applicants' claimed antigen's molecular weight. As seen in the BU101 polypeptide (SEQ ID NO: 2) database sheet this polypeptide contains the amino acid proline at position number 53 indicative of a polymorphism.

However, this patent does not teach the combination of these polypeptides as a purified MPA and composition of matter which has at least 20% identity with the amino sequences selected from the group consisting of SEQ ID NO: 3, 2 and 10. Nor does the patent teach compositions of matter wherein the composition comprises at least one antibody bound to said multimeric polypeptide antigen, two antibodies that bind to polypeptides having amino sequences of SEQ ID NO: 3, 2, 10 and fragments thereof with polypeptides having at least 20% identity with said amino acid sequences. It would have been *prima facie* obvious to one of ordinary skill in the art at the time the claimed invention was made to combine the polypeptides, variants, fragments and other compounds of the patent, such as antibodies, pharmaceutical carriers or homologs (see column 17, lines 40-46 and column 29, lines 25-27). One of ordinary skill in the art would have been motivated to do so with a reasonable expectation of success by teachings in the patent that such a combination of polypeptides and molecules could be employed alone or in conjunction for the manufacture of therapeutic agents which are

useful in research, diagnostic and clinical applications related to inflammation, the regulation of steroid levels in the uterus and neoplasia (see columns 3 and 4, bridging paragraph).

15. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Alana M. Harris, Ph.D. whose telephone number is (703) 306-5880. The examiner can normally be reached on 6:30 am to 4:00 pm, with alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa, Ph.D. can be reached on (703) 308-3995. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4315 for regular communications and (703) 308-4315 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Alana M. Harris, Ph.D.
September 10, 2001

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